K970842

MAY 28 1997

Section 513(j) of the Federal Food, Drug and Cosmetic Act
Summary of Safety and Effectiveness

March 5, 1997

I. General Provisions

Common or Usual name:	Infusion Catheter
Proprietary name:	Cordis Endeavor Infusion Catheter
Name and Address of Applicant:	Cordis Corporation Miami Lakes Operation Center 14201 NW 60 Avenue Miami Lakes, FL 33014

II. Name of Predicate Devices

SciMed Dispatch and Dispatch Gold Infusion Catheters
LocalMed InfusaSleeve and InfusaSleeve II Infusion Catheters
Interventional Innovations Segue Infusion Catheter

III. Classification

Infusion catheters are class II devices according to 21 CFR 870.1210.

IV. Performance Standards

Performance standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The Endeavor Infusion Catheter is intended to deliver solutions to the coronary and peripheral vasculature. The device is an over-the-wire design with a distal infusion region and a proximal hub. The infusion region is indicated by a central radiopaque marker band.

VI. Biocompatibility

All appropriate biocompatibility testing was performed, and successfully passed, on the materials used for the Endeavor Infusion Catheter.

VII. In vitro Testing

A series of *in vitro* and *in vivo* tests were performed to assure that the introduction of the Endeavor Infusion Catheters does not raise new issues of safety and effectiveness. All test results met or exceeded established specifications.

VIII. Summary of Substantial Equivalence

The Endeavor Infusion Catheter is designed for the infusion of solutions to the coronary and peripheral vasculature. The Endeavor Infusion Catheters have similar intended uses, design characteristics and dimensions as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1997

Ms. Tamara Yount
Cordis Corporation
P.O. Box 025700
Miami, Florida 33014

Re: K970842
Cordis Endeavor Infusion Catheter
Regulatory Class: II (two)
Product Code: 74 KRA
Dated: March 6, 1997
Received: March 7, 1997

Dear Ms. Yount:

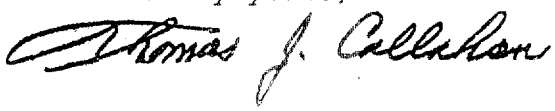
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use
Cordis Endeavor Infusion Catheter

The intended use statement of this product is:

The Cordis Endeavor Infusion Catheter is intended to deliver solutions, such as heparinized saline, and thrombolytic agents, such as urokinase, to the coronary and peripheral vasculature.

510(k) number K970842
(To be assigned by FDA)

(Division ... Cardiovascular, Respiratory,
Division ...
and ...
510(k) Number K970842

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